

NCRI Head & Neck Group

Annual Report 2020 - 2021



NCRI Partners

NCRI is a UK-wide partnership between research funders working together to maximise the value and benefits of cancer research for the benefit of patients and the public. A key strength of the NCRI is our broad membership with representation across both charity and government funders as well as across all four nations in the United Kingdom.



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NCRI Head & Neck Group

Annual Report 2020-21

1. Top achievements in the reporting year (up to three)

It has been a challenging year for the Head & Neck Research Group, as for healthcare and the community at large across the UK. The COVID-19 pandemic has made a huge impact on the presentation, diagnosis and management of patients with Head & Neck cancers, as well as impacts on the clinical workforce, and much academic time and energy has been diverted from Head & Neck cancer research to COVID-19 related work. Despite this, the Group has had some notable achievement.

Achievement 1

Several members of the Group were actively involved in instigating and/or contributing to COVID-19 associated research for Head & Neck cancer patients including published guidelines and impacts of the pandemic on surgical and oncological management of Head & Neck patients.

Achievement 2

Although most research activity was paused during the waves of the pandemic, even the complex Head & Neck studies were able to implement mitigation factors to allow speedy reopening / project development.

Achievement 3

The Group has been successful in gaining funding for several new clinical studies including important studies to better understand risk stratification and optimised follow up in locally advanced disease.

2. Structure of the Group

There was no planned rotation from the Group over this period but 2 of our Subgroup Chairs, Jon Wadsley (Thyroid Subgroup) and Ioanna Nixon (Epidemiology & Survivorship Subgroup) left the Group, with a replacement being found for the Thyroid Subgroup, which will continue as a Subgroup into the new structure, but no replacement for the Epidemiology & Survivorship Subgroup, given both short notice and the imminent restructuring of the Groups. In addition, one of our longstanding members, Bernie Foran, retired from the NHS and the Group during the year and a couple of our trainees moved on.

The Group has arranged for a final meeting prior to the restructure, with input from all members to highlight projects in development that would benefit from consideration for incorporation into an NIHR supported working group.

3. Head & Neck Group & Subgroup strategies

The COVID-19 pandemic has made a huge impact on the management of Head & Neck cancer patients. Many of the standard treatments involve very intensive therapies with multimodality approaches being common, including the need for in-patient support and particularly surgery often requiring ITU input. These standard practices were heavily compromised during the last 12 months and interventional studies based on these backbones were inevitably impacted.

This led to a temporary change in Group strategy early last year, taking the opportunity for Group members to lead the field and be actively involved in both creating guidance on optimised management of Head & Neck cancers during the pandemic and a wave of research projects exploring the impacts of these changes (and other changes in the Head & Neck cancer patient pathway) on outcomes. These are outlined in more details below.

In addition, despite the pandemic, several of the key strategies have been progressed:

- Effort has been made to ensure active involvement of Consumers within study development in the Subgroups, as well as input into more developed projects reviewed within the main Group.
- A working group has been developing a large observational study for pre-invasive disease, which is close to readiness for funding submission.
- Better understanding is required to differentiate patients who may require intensification of treatment or follow up and collaborative groups led by research Group members have been developing these ideas to successful grant application and ongoing project development.
- Closer liaison with Head & Neck pathology and basic science leaders is a key ongoing strategy for the Group. This has been ingrained within projects developed by the Group and is associated with the development of a Head & Neck science workshop (deferred due to COVID-19)
- Ongoing attention on a more systematic approach to rarer Head & Neck cancers is another key theme. This has led to an impressive expansion of activity within the Thyroid Subgroup, leading to the continuation of this Subgroup into the restructure. In addition, a workshop in salivary gland cancers has also been proposed to focus attention into the unmet needs and develop interventional studies.

Epidemiology & Survivorship Subgroup (Prev. Chair, Dr Ioanna Nixon)

During the COVID-19 pandemic the Group focussed on developing a project exploring the impact of the changes in patient pathways and management caused by the pandemic for Head & Neck patients specifically, but this was not successful in gaining funding. Some of this attention is now supporting these important questions in projects covering multiple cancer types including Head & Neck. In the absence of a Subgroup Chair, whilst work has been ongoing by members this has not been as cohesive as usual.

The Epidemiology & Survivorship Subgroup has however been involved in the development of both the PET-NECK2 programme (now NIHR funded) and the ongoing development of the observational study in preinvasive disease.

Surgery & Localised Therapies Subgroup (Chair, Professor Jim McCaul)

This has been a very challenging year in head and neck cancer surgery. Many centres had reduced activity, or none, due to critical care bed access and new cancer patients coming from primary care appeared at first to reduce in some centres. In response to this the CovidSurg Collaborative

was set up. Members of the NCRI Surgery & Localised Therapies Subgroup (R J Shaw, A Schache) organised and led this International collaborative effort which is an ongoing programme of research. All members of the Subgroup contributed data to this unprecedented research effort during the pandemic. This work highlighted that some centres (e.g. Glasgow) did not stop major cancer work at all, where some other centres stopped entirely. A telling fact was that of all cancer surgery internationally, head and neck cancer is normally around 5% of the total. During COVID-19 this reached >25% of all cancer surgery continuing. We interpret this to be international recognition of the rapidly life changing and life ending nature of head and neck cancer and the need for expeditious treatment to maintain both the aesthetic and functional importance of the face, head, neck and contained structures. These findings are published in Cancer (2020 doi, 10.1002/cncr.33320) and Clin Otolaryngol Feb 15 2021.

Many of our trials were delayed and repurposed recently post pandemic peak. These include RAPTOR NIHR131050 “RAPTOR: Randomised Controlled Trial of PENTOCLO in Mandibular Osteoradionecrosis” NIHR EME: £1,004,830 Feb 2021 CI Professor R J Shaw. Another such is SAVER (Sodium Valproate for Epigenetic Reprogramming in the management of High Risk Oral Epithelial Dysplasia EudraCT no 2018-000197-30) This trial is soon to begin recruitment.

Another focus for our Subgroup is prehabilitation and optimisation of patients in the short run up after diagnosis and before major head and neck cancer surgery. This is exemplified by a trial of pre- and post-op exercise and amino acid supplement gel in early work up recently presented to our Subgroup by A Kanatas. Another prehabilitation trial is Pre-Enhance, CI Jo Patterson.

Our existing portfolio includes ELATION the largest ever trial of thyroid nodule assessment, currently in write up and COMPARE (behind schedule but back recruiting well now), a trial for HPV negative intermediate and high-risk oropharynx cancer. PATHOS is now an international success story. We were very supportive of ReSPECT study (CI Claire Paterson), which was unfortunately unsuccessful in this CRUK funding round. HARE40 (Therapeutic HPV vaccine trial +/- anti-CD40 in HPV driven SCC) still has one trial arm open. PET NECK2 is funded and in set up and LOOC (sentinel node biopsy in oropharynx cancer) is opening in some centres.

Closed trials on immunotherapy in combination with major head & neck surgery include AMG319 (in write up) and NICO (closed to recruitment and in follow up).

The NCRI Head & Neck Surgery and Localised Therapy Subgroup has an enthusiastic, energised, high achieving and balanced collaborative membership. We are Maxillofacial and ENT surgeons, with pathology and clinical oncology input and our trainee member, Mr J Higginson.

References:

- Head and neck cancer surgical capacity during the second wave of the COVID-19 pandemic – have we learned the lessons? COVIDSurg collaborative. Clin Otolaryngol Feb 15 2021. Preprint:<https://doi.org/10.22541/au.161330251.12938799/v1>
- Head and neck cancer surgery during the COVID-19 pandemic: an international, multicentre, observational cohort study. COVIDSurg Collaborative. Cancer; 2020 doi. 10.1002/cncr.33320

Systemic Therapy & Radiotherapy Subgroup (Chair, Dr Anthony Kong)

Key strategic aims and progress:

To propose new trials involving novel agents and immunotherapy +/- standard treatment

Several studies are in development involving novel combinations with immunotherapeutics. One example is we invited a few speakers to present to us on “Hyperthermia in head and neck cancers”

by Prof. Gerard Van Rhoon (Erasmus MC Cancer Institute), Paul van den Biggelaar (CEO/co-founder, Sensius) and Colin Callow (Innovation Agency) on 25 June 2020.

Since this meeting, Sensius has been liaising with four cancer centres, Liverpool, Birmingham, Guy's and Charing Cross with a view to install hyperthermia machines at these four centres. Sensius has secured investors' funding to install these machines. We are also in the process of applying for an NIHR grant to conduct a clinical study (stage 1 application to be submitted by 9 June 2021). The clinical study will be an early phase study combining radiotherapy with hyperthermia for head and neck cancer patients not suitable for concurrent chemotherapy.

To advance and put translational research at the core of each study

We hope to incorporate translational research in the above proposed study of hyperthermia with radiotherapy.

In our Feb 2021 meeting, we had two presentations related to translational research:

- 1) Comparison of PD-L1 combined positive scores (CPS) between a cohort of oral squamous cell carcinoma (OSCC) primary and recurrence specimens – Drs Lisette Collins and Artysha Tailor

There was a lot of interest and discussion on this topic. Members also suggested some additional lines of research related to this topic. It is hoped that this study may be extended to multi-centre study in the future.

- 2) Research in osteoradionecrosis – Dr. Vinod Patel and Dr. Rachel Brooker

The presentation was well received and generated discussion/interest. There was recommendations from members on further research topics.

To increase interaction with other groups for clinical and translational research (NCRI CTRad, NCRI CMPath) and increase collaboration with international centres including EORTC

Several UK-led H&N studies have successfully expanded internationally through collaborations with networks such as the EORTC, and the group continues to explore new potential interactions. We have proposed to start a survey and audit on treatment modifications in head and neck cancers during the COVID-19 pandemic and there was support from members. We have had discussion with NCRI CTRad initiative COVID-RT to collaborate to collect the outcome for the patients in the future.

To increase the success rate of investigator-led studies and to overcome the problems encountered

We invited Claire Paterson to give a talk on her proposed clinical study "Radiotherapy Dose De-Escalation in HPV Positive Oropharyngeal Squamous Cell Cancers, Maintaining Outcomes and Reducing Toxicity"- The ResPeCT trial .

The presentation generated quite a lot discussion and interest and several members made suggestions to Claire. We have also subsequently provided a support letter for Claire to submit a clinical trial award grant. We hope that she will be successful in the grant application.

Thyroid Subgroup (Chair, Prof Jon Wadsley initially, now Dr Kate Garcez)

Key strategic aims and progress:

Develop a multi-centre trial for high risk differentiated thyroid cancer

Further work has been done to develop a protocol for dosimetry guided I131 therapy for advanced disease, building on work done in the SELIMETRY trial. Progress has been made with regard to establishing the most appropriate endpoint for the study. A review entitled 'Prospects for personalised treatment of patients with radioiodine-avid locally recurrent or metastatic thyroid cancer' was published in a special edition of Clinical Oncology in February 2021, setting out the rationale for undertaking such a trial.

Increase surgical trials on the portfolio

Following confirmation of funding for the HoT trial (NIHR HTA), further progress has been made and it is hoped that the first few sites could be open by July 2021.

Recruitment to the Thy3000 project is progressing well and data analysis is planned to start within the next 6 months. This is a surgical trainee led project collecting data on the primary management of thyroid nodules across the UK.

Discussion has begun regarding possible neoadjuvant trial for patients with operable medullary thyroid cancer (MTC).

Facilitate access to novel therapies for anaplastic thyroid cancer

The international Anaplastic Thyroid Cancer Tissue Bank and Database Project (iNATT) continues to collect tissue from this rare variant of thyroid cancer. Members of the Subgroup had previously negotiated access to the combination Dabrafenib and Trametinib on a compassionate use basis for patients with BRAF mutant anaplastic thyroid cancer (ATC) in patients maintaining good PS. Unfortunately, this scheme will end in June 2021. A policy proposal form has been submitted to NHSE on behalf of the Subgroup. The Subgroup continue to prospectively collect data from this cohort, through iNATT.

A potential international commercial trial opportunity, investigating use of an immunotherapy agent in ATC arose. Several members submitted expressions of interest but unfortunately the sponsor ultimately decided not to open the study in UK sites.

Coordinate molecular pathology studies through the group

Following a successful single site pilot study, work continues to develop a multicentre study investigating the use of ctDNA as a biomarker for response and development of resistance to multi-kinase inhibitors in advanced thyroid cancer. Funding has now been agreed for some aspects of this study, and the aim is to achieve NIHR portfolio status.

Subgroup members have contributed significantly to raising awareness of access to testing for NTRK, RET and BRAF alterations via the Genomic Laboratory Hubs (GLHs) and have submitted proposals to Genomics England to add additional tests to the Test Directory for thyroid cancer.

Nurture links with pharma to increase opportunities for further commercial and investigator led studies

Links have been established with companies developing new targeted therapies, in particular RET specific inhibitors. Four UK sites have been selected for an international phase 3 study (LIBRETTO-531) investigating selpercatinib in RET mutated medullary thyroid cancer. Discussion is ongoing regarding other studies of different RET inhibitors.

As above, disappointingly a commercial sponsor investigating an immunotherapy agent in ATC decided not to bring the study to the UK.

Develop studies addressing the risks of over diagnosis and over treatment in thyroid cancer

The IoN trial has recently completed recruitment, addressing the question whether radioiodine can be omitted for patients with low risk thyroid cancer following total thyroidectomy. Follow up is ongoing.

The HoT trial, investigating the possibility of de-escalation from total thyroidectomy to hemithyroidectomy alone in low risk cases is set to open in the first few sites by July 2021.

The Thy3000 study aims to collect data regarding management of thyroid nodules presenting to secondary care and hopes to provide useful data to support better management and reduced risk of over-diagnosis.

4. Cross-cutting research

The Head & Neck Research Group has had no task groups or working parties during the reporting year.

5. Funding applications in last year

Table 1 Funding submissions in the reporting year

Study	Committee & application type	CI	Outcome	Level of Group input	Funding amount
Cancer Research UK*					
March 2021					
INSPIRE - (Investigating National Solutions for Personalised Iodine-131 Radiation Exposure) Measuring absorbed dose to tumour and organs at risk following routine iodine ablation therapy.	Biomarker Project Award	Professor Jonathan Wadley	Not Supported	Significant	
PROTIS: A phase III trial of proton beam therapy versus intensity-modulated radiotherapy for the treatment of sinonasal malignancy	Clinical Trial Award - Outline	Dr David Thomson	Full Application Invited	Significant	
December 2020					
PATHOS -T: A Bioresource Collection associated with PATHOS, a Phase II/III trial of risk-stratified, reduced intensity adjuvant treatment in patients undergoing transoral surgery for Human papillomavirus (HPV)-positive oropharyngeal cancer	Sample Collection Award (May 2020)	Professor Terence Jones	Supported		
NIPRO: Nivolumab with PROton beam therapy in patients aged over 70 years with oropharyngeal cancer – a single arm phase II trial	Endorsement (May2020)	Dr David Thompson	Not supported		
Other committees**					
Study	Committee & application type	CI	Outcome	Level of Group input	Funding amount
RAPTOR	NIHR EME	Richard Shaw	Successful	Over years, very significant.	£1,004,830
PETNECK2	NIHR PGiAR	Hisham Mehanna	Successful	Significant, over years	~£2.5m

**CRUK CRC applications for table 1 completed by NCRI Executive.
**Other applications in the table to be completed by Group Chair*

6. Consumer involvement

Emma Kinloch & Tim Humphrey

The Consumer members of the Head & Neck Group and its' Subgroups have played a full role in the work of their respective Groups this year. Activities include developing new studies, contributing to Group and Subgroup review of proposals seeking funding and review and development of patient information material. In addition, Consumer members are part of trial management groups and trial steering groups, they have actively input into the future strategy of the Group and provided representation at Proposals Guidance meetings. Consumers also support ad hoc requests from Group/Subgroup members.

Emma Kinloch and Tim Humphrey sit on the main Head & Neck Group. Emma Kinloch has been a member since 2015 and is also NCRI Consumer Lead. She runs a head and neck cancer support group based in London and is the founder of Salivary Gland Cancer UK, bringing a wide variety of patient voices to the group. In October 2020 she Chaired the NCRI webinar 'Demystifying PPI' and has participated in two Head & Neck Proposals Guidance meetings during the course of the year. Emma sits on the Trial Management Group of ToRPEDO and was on the NICO trials Steering committee until it's early closure in November 2020, both of which as a direct result of the groups work on the projects.

Tim Humphrey became a member of the Group in 2017 and is also a member of NCRI's CTRad. He is the DNA Damage Response (DDR) theme lead in the Department of Oncology, leading a team of research groups and is the deputy director at the Oxford Institute for Radiation Oncology. As a cancer research scientist, he provides both the Consumer perspective and has been on occasion, scientific advice for several research and clinical trial applications. Tim is a member of the Patient Advisory Group for the PETNECK 2 study (comparing PET-CT guided surveillance with planned ND) and the patient representative for the NIPRO trial (Nivolumab with proton beam vs standard of care). Tim has made a number of presentations this year to the NCRI Consumer Group and has Chaired the NCRI session 'NCRI Beyond the Horizon Innovative Cancer Drug Discovery'. As a patient advocate, Tim is keen to ensure that clinical trials are based on high quality preclinical data.

Chris Curtis and Christine Allmark provide Consumer representation on the Epidemiology and Survivorship Subgroup. Christine brings a wealth of experience from her many patient advocacy roles, Chris is the founder of The Swallows Head and Neck Cancer Support Charity. The Thyroid Subgroup has Kate Farnell and Helen Hobrough as Consumer members. Both have strong links into patient support charities, Butterfly Thyroid Cancer Trust and Thyroid Cancer Group Wales, which allows for providing a wide range of patients' views and accessing those groups to periodically input into the Subgroups work.

7. Collaborative partnership studies with industry

Several current and previous NCRI Research Group members have been actively engaging with both small biotech and big Pharma to develop collaborative projects and clinical studies. These are exemplified by early phase studies such as EACH, HARE40, NICO, ORCA2, POPPY, WISTERIA and larger phase III studies such as COMPARE.

Trying to develop a more strategic approach to maximise relationships between different members with different companies has been challenging but remains of strategic interest to the Group.

8. Priorities and challenges for the forthcoming year

Priority 1

Continue the development of a large pre-malignant observational study and consider other observational studies in rarer cancers.

Priority 2

Proton Beam Therapy (PBT) trials

With the TORPEdO study open and recruiting in OPSCC, continue development of PBT studies in other HN areas of unmet need

Challenge 1

Transition enthusiasm from members developing multiple ideas and projects into a more defined number of working groups for the NCRI Research Group transition.

Challenge 2

There has been pressure on Head & Neck clinical trials teams and supporting services across the UK for some time, with many units at capacity and unable to develop / contribute to new academic studies, even before the COVID-19 pandemic. This adds a huge challenge to the feasibility of delivering current studies and studies in development.

Dr Martin Forster (Head & Neck Group Chair)

Appendix 1

Membership of the Head & Neck Group

Name	Specialism	Location
Dr Rachel Brooker*	Clinical Oncologist	Liverpool
Dr Anthony Kong	Clinical Oncologist	Birmingham
Dr Nachiappan Palaniappan	Clinical Oncologist	Cardiff
Dr Stefano Schipani	Clinical Oncologist	Glasgow
Dr David Thompson	Clinical Oncologist	Manchester
Dr Jon Wadsley	Clinical Oncologist	Sheffield
Dr Timothy Humphrey	Consumer	Oxford
Ms Emma Kinloch	Consumer	London
Dr Martin Forster (Chair)	Medical Oncologist	London
Dr Robert Metcalf	Medical Oncologist	Manchester
Dr Joseph Sacco	Medical Oncologist	Liverpool
Dr Jacqueline James	Pathologist	Belfast
Dr Max Robinson	Pathologist	Newcastle
Dr Wai Lup Wong	Radiologist	Stevenage
Dr Christina Yap	Statistician	Birmingham
Dr Emma King	Surgeon	Southampton
Mr Barry Main*	Surgeon	Bristol
Professor Jim McCaul	Surgeon	Glasgow
Mr Paul Nankivell	Surgeon	Birmingham
Mr Andrew Schache	Surgeon	Liverpool
Mr Stuart Winter	Surgeon	Oxford

Consumer Representation

Name	Location
Dr Timothy Humphrey	Oxford
Ms Emma Kinloch	London

Trainee Members

Name	Specialism	Location
Dr Rachel Brooker*	Clinical Oncologist	Liverpool
Mr Barry Main*	Surgeon	Bristol

Membership of the Subgroups

Epidemiology & Survivorship Subgroup		
Name	Specialism	Location
Professor Gerry Humphris	Clinical Oncologist	St Andrews
Dr Ioanna Nixon (ex-Chair)	Clinical Oncologist	Glasgow
Dr Richard Simcock	Clinical Oncologist	Sussex
Professor David Conway	Director of Dental Research	Glasgow
Mrs Christine Allmark	Consumer	Yorkshire
Mr Chris Curtis	Consumer	Blackpool
Professor Mary Wells	Health Services Researcher	London
Professor Luc Bidaut	Medical Physicist	Lincoln
Professor Jo Patterson	Speech and Language Therapist	Liverpool
Professor Hisham Mehanna**	Surgeon	Birmingham
Professor Simon Rogers	Surgeon	Liverpool
Mr Stuart Winter	Surgeon	Oxford
Mr Richard Townsley**	Surgeon	Glasgow

Systemic Therapy & Radiotherapy Subgroup		
Name	Specialism	Location
Dr Shreerang Bhide	Clinical Oncologist	London
Dr Bernadette Foran	Clinical Oncologist	Sheffield
Dr David Thomson	Clinical Oncologist	Manchester
Dr Mary Lei**	Clinical Oncologist	London
Dr Rachel Brooker*	Clinical Oncologist	Liverpool
Dr Anthony Kong (Chair)	Clinical Oncologist	Birmingham
Dr Stefano Schipani	Clinical Oncologist	Glasgow
Dr Imran Petkar**	Clinical Oncologist	London
Dr Ketan Shah	Clinical Oncologist	Oxford
Dr Joseph Sacco	Medical Oncologist	Liverpool
Dr Lisette Collins**	Pathologist	Sheffield
Ms Lisa Hay	Radiographer	Glasgow
Dr David Andrew	Radiologist	Sheffield
Dr Steve Connor**	Radiologist	London
Ms Suzanne Currie**	Radiotherapy Physics Research Lead	Glasgow
Dr Catharine West	Scientist	Manchester
Mrs Clare Griffin	Statistician	London
Dr Emma King	Surgeon	Southampton
Dr Vinod Patel**	Surgeon	London

Surgery & Localised Therapies Subgroup		
Name	Specialism	Location
Dr Claire Paterson	Clinical Oncologist	Glasgow
Dr Max Robinson	Pathologist	Newcastle
Dr Emma King	Surgeon	Southampton
Professor Jim McCaul (Chair)	Surgeon	Glasgow
Professor Hisham Mehanna**	Surgeon	Birmingham
Mr Paul Nankivell	Surgeon	Birmingham
Mr Mike Nugent	Surgeon	Sunderland
Mr Andrew Schache	Surgeon	Liverpool
Professor Richard Shaw**	Surgeon	Liverpool
Mr Iain Nixon	Surgeon	Edinburgh
Mr Anastasios Kanatas	Surgeon	Leeds
Mr James Higginson*	Surgical trainee	London

Thyroid Subgroup		
Name	Specialism	Location
Dr Matthew Beasley**	Clinical Oncologist	Bristol
Dr Kate Garcez (Chair)	Clinical Oncologist	Manchester
Dr Georgina Gerrard**	Clinical Oncologist	Leeds
Dr Laura Moss	Clinical Oncologist	Cardiff
Ms Kate Farnell	Consumer	Newcastle
Ms Helen Hobrough**	Consumer	
Dr Saba Balasubramanian**	Endocrinologist	Sheffield
Dr Kristien Boelaert	Endocrinologist	Birmingham
Professor Mark Strachan	Endocrinologist	Edinburgh
Professor Chris McCabe **	Endocrinologist	Birmingham
Professor Allan Hackshaw	Epidemiologist	London
Dr Glenn Flux**	Medical Physicist	London
Professor David Gonzalez-de-Castro	Molecular Oncologist	Belfast
Ms Ingrid Haupt-Schott	Nurse	Cardiff
Dr Sarah Johnson	Pathologist	Newcastle
Dr David Poller	Pathologist	Portsmouth
Professor Dae Kim	Surgeon	London

* denotes trainee member

**denotes non-core member

Appendix 2

Head & Neck Group & Subgroup Strategies - 2019 - 2022

Objective	Key actions	Leads	Timeline
1. Membership	<ul style="list-style-type: none"> No plans to replace exiting members of the group pre-transition Look at establishing the membership of working groups for priority projects Ensure opportunities for fellowships and new PIs continue within new format working groups Ensure Consumer involvement in project development and new format working groups 	MDF	2021
		MDF / All	2022
		MDF / All	Ongoing
		MDF / All	Ongoing
2. Oral & Dental Health	<ul style="list-style-type: none"> Deliver the SAVER study Work closer with oral medicine groups to develop radioprotectors and treatment to reduce long-term post-treatment morbidities 	All	2021 Ongoing
3. H&N 5000 - research opportunities	<ul style="list-style-type: none"> Continue to use the huge resource offered by HN5000 database 	All	Ongoing
4. New trial development / trial design in key research areas	<ul style="list-style-type: none"> Immunomodulation studies for post op high risk disease Window of opportunity studies Studies to improve surveillance and detection of recurrence 	All	Ongoing
5. Translational research, biobanking and sample tissue collection	<ul style="list-style-type: none"> Science & Pathology Workshop Molecular stratification for high risk disease Develop standard strategies and protocols for translational sample collection and processing 	MR, MDF All	2022
		HM, PN, MDF	
6. Observational studies	<ul style="list-style-type: none"> Develop new large observational study in pre-malignant disease 	ST, PN, All	2022
7. Rarer cancers	<ul style="list-style-type: none"> Salivary Gland cancer Workshop Develop International collaborations for SGC, Thyroid and rarer HN Cancers 	RM, EK, MDF KG, RM, MDF	2022 Ongoing
8. Industry engagement	<ul style="list-style-type: none"> Improve networking to develop better access to industry for collaborative research 	All	Ongoing

<p>9. International presence and collaborations</p>	<ul style="list-style-type: none"> • Maintain and improve presence of UK HN researchers on international stage • Build on recent successful collaboration with EORTC to develop joint projects in areas of shared interest and rarer populations • Continue engagement with NHC Inter Group to increase harmonisation 	<p>All</p> <p>MDF / All</p> <p>MDF / All</p>	<p>Ongoing</p>
<p>10. Thyroid Subgroup</p>	<ol style="list-style-type: none"> 1. Co-ordinate molecular pathologies studies through the group 2. To develop further I131 dosimetry studies, in both low-risk and high-risk disease settings 3. Increase surgical trials on the portfolio 4. Facilitate access to novel therapies for anaplastic thyroid cancer 5. Nurture links with pharma to increase opportunities for commercial and investigator led studies 6. Develop studies addressing the risks of over diagnosis and over treatment in thyroid cancer 7. Seek expertise in qualitative study design to facilitate eg work on impact of individualised decision making on patients 8. To enhance translational research opportunities 	<p>See section 3 for details regarding progress made during the past year.</p>	<p>Ongoing</p>
<p>11. Systemic Therapy & Radiotherapy Subgroup</p>	<ol style="list-style-type: none"> 1) Collaboration with international centres including EORTC and developing countries - to work out the best ways to collaborating since there are obstacles (funding, legal issues, approval, delay in set-up). Other way maybe to set up parallel studies with international centres with same or very similar endpoints 2) Overcome the problems encountered with investigator-led studies (limited 	<p>Martin Foster will have meetings with EORTC</p> <p>Collaboration and advice</p>	<p>2019 - 2022</p>

	<p>funding, excess treatment costs, delay-in set up, recruitment issues, IP issues, third party/vendor, translational research)</p> <p>3) Advancing translational research study - to integrate the translational research proposal into the trial grant application early on even if no adequate fund is available or applied at this stage - this will be helpful for subsequent or separate grant application for the biomarker research work - importance of the validation of biomarker research</p>	<p>between all group members</p> <p>Catherine West</p>	
<p>12. Surgery & Localised Therapies</p>	<p>1) Rebuilding clinical trial recruitment across the UK in the ongoing pandemic. All research other than Covid related stopped in centres where our committee members are located. Two new trials delayed by COVID will help with this process (SAVER and RaPTOR)</p> <p>2) Prioritise trials on early cancer and precancer, to include Industry collaboration (LISTER2 – collaboration with biostatus – Spherulugel)</p> <p>3) Advance Research on Prehabilitation and optimisation for patients to undergo Major Head and Neck Cancer surgery</p>	<p>All</p> <p>JAM</p> <p>AK, MN, AS</p>	

Appendix 3

Top 5 publications in the reporting year

Trial name & publication reference	Impact of the trial	CSG involvement in the trial
<p>1. Rogers SN, Allmark C, Bekiroglu F et al. Improving quality of life through the routine use of the patient concerns inventory for head & neck cancer patients: main results of a cluster preference randomised controlled trial. <i>Eur Arch Otorhinolaryngol.</i> 2020 Dec;277(12):3435-3447. doi: 10.1007/s00405-020-06077-6. Epub 2020 Jun 1.</p>	<p>The Patient Concerns Inventory (PCI) is a prompt list allowing head and neck cancer (HNC) patients to discuss issues that otherwise might be overlooked. This trial evaluated the effectiveness of using the PCI at routine outpatient clinics for one year after treatment on health related QOL (HRQOL). This novel trial supports the integration of the PCI and UW-QOLv4 into routine consultations as a simple low-cost means of benefiting HNC patients. It adds to a growing body of evidence supporting the use of patient prompt lists more generally. The PCI provided an effective means to conduct the clinical consultations by avoiding unnecessary healthcare costs and focussing on what aspects of care were most important to patients. The cost per QALY gain was within the NICE guideline threshold of £20,000-£30,000. The PCI is a low-cost intervention with modest training requirements for health professionals and appears to generate a cost-effective benefit to patients from an NHS perspective if rolled-out as part of routine care. Its use in routine practice is supported by consultants.</p>	<p>Mentorship, advice, enthusiastic support.</p>
<p>2. Moss L, Cox C, Wadsley J et al. Medullary Thyroid Cancer Patient's Assessment of Quality of Life Tools: Results from the QaLM Study. <i>Eur Thyroid J</i> 2021;10:72-78. doi.org/10.1159/000509227</p>	<p>The results demonstrated that there was no single quality of life questionnaire preferred by patients, suggesting that any of the tools studied may be useful for patients with medullary thyroid cancer. The study did show that there was a difference between the questionnaire least preferred by patients. The study also highlighted that it would be useful to conduct future studies restricting the study population to those patients with metastatic or progressive disease, as these patients tend to be more symptomatic and the utility of different methods of assessment of quality of life may be more clearly defined.</p>	<p>The Thyroid Subgroup had an active part in study design and subsequent review of the progress of the study. The chief investigator and several of the sub-investigators and co-authors were/are members of the Thyroid Subgroup.</p>

Appendix 4

Recruitment to the NIHR portfolio

Summary of patient recruitment by Interventional/Non-interventional and number of studies opened/closed.

Year	All participants		Cancer patients only*		Number of studies	
	Non-interventional	Interventional	Non-interventional	Interventional	Opened	Closed
2016/17	973	1010	973	1010	11	12
2017/18	2326	1440	2326	1440	15	12
2018/19	470	1014	470	1014	11	13
2019/20	273	566	273	566	19	24
2020/21	386	308	386	308	13	4

*This data is based on a proxy from CPMS (the NIHR database used to collect patient recruitment data) and includes diagnostics, screening and prevention patients.

Appendix 5

Annual report feedback 2019-20

02 November 2020

Dear Martin

Re: Head & Neck Group Annual Report 2019/20

I am writing to you with regards to the Head & Neck Group Annual Report 2019-20.

Due to the challenging time for all in the healthcare sector resulting from COVID-19 and the unprecedented impact on the activity of both the Groups itself and wider research activities, ranging from the time available for research work versus clinical commitments to the funding of new trials and the recruitment of existing trials, the NCRI allowed the Groups to submit reduced report this year if they were able to do so.

We received 12 out of 15 Group reports which was reviewed at a two day meeting on the 12th and 13th October 2020 by a panel consisting of some former NCRI Group Chairs, NCRI CPath Chair, former NCRI CTRad Chair and the current Strategic Advisory Group Chair, NCRI Head of Research Groups and representatives from the NIHR Cancer Coordinator Centre, NCRI Consumer Forum, NHS Cancer Alliances, epidemiology, CTU/basic science, allied health profession and the Canadian Cancer Clinical Trials Network.

Due to no report being received for the Head & Neck Group, the panel was unable to review the Group's progress this year. However, they would like to share a summary of the generic points raised at the review. Please share the contents of this letter with your members for discussion at the next Group meeting.

Generic feedback for all the Groups

Strategic objectives and the impact of COVID 19

- Due to the research funding challenges and restrictions on NHS resources resulting from COVID 19, the Panel recommended the Groups evaluate their strategic objectives and focus on the most important priorities or questions that need to be answered as it would not be feasible for the Groups to be doing everything they planned or continue to "plug in the gaps." Additionally, the Panel suggested looking for more cost-efficient methods of working where they can.

- The Panel felt that the strategic objectives for most Groups were too broad especially in the current climate. The Groups were asked to provide specific, measurable aims for their strategic objective and attach timelines/metrics to them.

Multidisciplinary approach to research and membership

- The panel noted the importance of collaborative and multidisciplinary working, especially in the current climate, and would encourage all Groups to continue to reach out to other relevant NCRI Groups and consider the NCRI strategic priorities where appropriate.

Linking with the wider research community

- The Groups were asked to link with the wider research community and engage with relevant networks, in particular, with researchers who are developing or are running large national platform studies when there is one available in the disease site e.g. PrecisionPanc (Upper GI Group) and TRACERx (Lung Group). The NCRI recognised that there is a role for them to play in promoting collaboration and will be working with the partners to encourage greater interaction between the Groups and the networks in future.

Funding opportunities

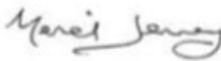
- Given the potential decrease in funding opportunities, the Groups are encouraged to explore alternative funding sources and collaborations e.g. with industry, government funders, NHS Cancer Alliances etc.

Consumers involvement:

- The panel encouraged Groups to integrate public and patient involvement (PPI) in all aspects of the Group's activities e.g. study design, proposal development, prioritisation of strategic areas etc.
- The Panel wanted to ensure that the consumer activity was captured throughout the report and not just in the consumer section, especially where the consumer reports are missing.

If you have any comments on this year's process, please send them to Nanita Dalal (Nanita.Dalal@ncri.org.uk) for collation.

Best wishes,



Professor Meriel Jenney
Annual Reports Review Committee Chair, NCRI
Consultant Paediatric Oncologist,
University Hospital of Wales



Dr Gillian Rosenberg
Head of Research Groups, NCRI

Appendix 6

Quinquennial review feedback - 2016

1. Comments and recommendations

The Panel thanked the CSG team for the documentation provided and the openness with which they had engaged in discussions. The Panel identified a number of strengths of the Group and issues which the CSG need to consider:

Strengths

- The panel noted overall how impressed they were with the Head & Neck CSG and how well it is functioning
- The strong portfolio of studies and clear plans for future work were noted
- The CSG's portfolio of studies has had clear International impact in recent years
- The panel felt there were many areas of good practice that other CSGs could learn from, in addition to the trainee scheme:
 - Their approach to membership rotations and fewer over-committed members
 - RTQA approvals coordination across trials
 - TCs between CSG meetings/in advance of funding deadlines (it was felt that the success rate of applications must be at least partially attributed to this)

Issues for the CSG to consider

- The Panel encouraged the Group to focus on more cross disease working e.g. explore opportunities with the oral & dental health specialty as well as other CSGs
- The CSG should ensure they are involved in discussions with regards HN5000 data access
- The Group should focus on raising their profile with ITOG, specifically for KN to join the protocol committee on behalf of the Thyroid Subgroup
- The Group should pursue their important ph0/1/2 work and explore different opportunities for funding e.g. something similar to the Trials Acceleration Programme (TAP) funded by Bloodwise
- It was suggested that MF should take over as the Group's link to the IRCI salivary gland work, or find someone within the Subgroup
- Inconsistency with geographical engagement must be addressed as this would likely improve the outcomes of the CSGs trials – it was suggested that a role for the trainees could be to identify the researchers in each network and ensure the CSG establishes links with them
- The Group should look to recruit clinician scientists at CSG or Subgroup level
- Whether the Survivorship Subgroup should be renamed Epidemiology Subgroup, or similar, to better reflect the breadth of its remit

Issues for the NCRI/NIHR CRN to consider

- It was felt that additional and more regular network recruitment data may help CSGs discover where recruitment issues lie and enable them to target and build links with specific networks who may be poor recruiters

In concluding the review, MS thanked everybody for participating and the NCRI CRG Team for preparing the paperwork and organising the Review.

The business of the meeting took four hours. ***The Group will be reviewed in five year's time.***



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